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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,222	09/01/2006	Chikara Murakata	P28672	8988
7055 7590 08/27/2009 GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191				
EXAMINER HAYLIN, ROBERT H				
ART UNIT		PAPER NUMBER		
1626				
NOTIFICATION DATE		DELIVERY MODE		
08/27/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
pto@gbpatent.com

Office Action Summary

Application No.

10/553,222

Applicant(s)

MURAKATA ET AL.

Examiner

ROBERT HAVLIN

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 26 is/are pending in the application.
- 4a) Of the above claim(s) 1-12, 20, 21 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-19, 22 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-85/08)
Paper No(s)/Mail Date See Continuation Sheet
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :9/1/06, 4/10/07, 5/10/07, 9/8/08, 11/17/08, and 6/26/09 .

DETAILED ACTION

Status of the claims: Claims 1-23, and 26 are currently pending.

Priority: This application is a 371 of PCT/JP04/05489 (04/16/2004) and claims foreign priority to JAPAN 2003-114071 (04/18/2003) and JAPAN 2003-164727 (10/06/2003).

IDS: The IDS dated 9/1/06, 4/10/07, 5/10/07, 9/8/08, 11/17/08, and 6/26/09 were considered.

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 13-23) in the reply filed on 6/5/09 is acknowledged. The traversal is on the ground(s) that the examiner has not established that the claims lack unity of invention under 37 CFR 1.475. This is not found persuasive because 1.475 requires the examiner to determine if unity of invention exists (a single general inventive concept under PCT Rule 13, as per MPEP 1893.03). The claims are not for a single product, but for a large number of compounds in excess of a billion different species written in the so-called "Markush practice" form. Therefore, the section (f) of Annex B provides detailed guidance for the particular situation in the instant application, namely "Markush Practice":

(f) "Markush Practice." The situation involving the so-called "Markush practice" wherein a single claim defines alternatives (chemical or non-chemical) is also governed by Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

(i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) all alternatives have a common property or activity, and

(B) (1) a common structure is present, i.e., a significant structural element is shared by all of the alternatives, or

(B) (2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

(ii) In paragraph (f) (i) (B) (1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a

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common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together.

(iii) In paragraph (f)(i)(B)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

(iv) The fact that the alternatives of a Markush grouping can be differently classified shall not, taken alone, be considered to be justification for a finding of a lack of unity of invention.

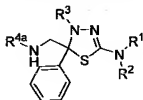
(v) When dealing with alternatives, if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered by the examiner. Reconsideration does not necessarily imply that an objection of lack of unity shall be raised.

In the instant case, the alternatives do not share a "significant structural element" and the compounds of the genus do not all belong to an art recognized class of chemical compounds. For example, compound No. 283, 199, 45, 37, and 22 have substantially different structural elements and the possible alternatives encompassed in the definitions of the variables are such that the common structural element cannot be said to be a significant portion of the structure, nor is it structurally distinctive in view of the existing prior art. In addition, the scope of the compounds of the groups read on different subject matter (formula I vs. formula IA) constituting further different groups of diverse products. Therefore, unity of invention is lacking and restriction is proper.

The requirement is still deemed proper and is therefore made FINAL.

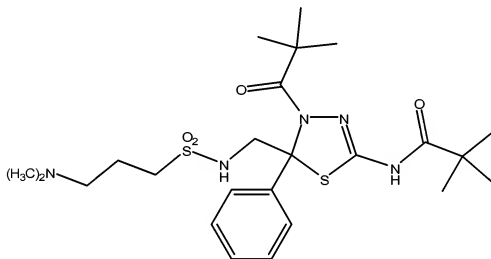
Applicant also elected the species of compound No. 237 allegedly reading on claims 13-19, 22, and 23 with the following structure:

Table 13 (Continued)



Example No.	Compound No.	R ¹	R ²	R ³	R ^{4a}
42	237	H	COC(CH ₃) ₃	COC(CH ₃) ₃	SO ₂ (CH ₂) ₃ N(CH ₃) ₂

Redrawn as:



As detailed in the following rejections, the generic claim encompassing the elected species was not found patentable. Therefore, the provisional election of species is given effect, the examination is restricted to the elected species only, and claims not reading on the elected species are held withdrawn. Accordingly, claims 20-21 are hereby withdrawn.

Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection through amendment, the amended Markush-type claim will be

reexamined to the extent necessary to determine patentability of the Markush-type claim. See MPEP 803.02.

2. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claim Rejections - 35 USC § 103

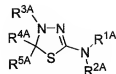
3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

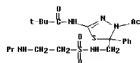
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 13-17 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murakata et al. (WO 03/051854, cited in the IDS in Japanese, abstract from CAPLUS Accession # 2003:491200) in view of Silverman, R. B. (The Org. Chem. of Drug Design and Drug Action, Academic Press, Inc.: San Diego, 1992, pp. 4-51).



(IA)

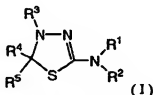
The claims are for a genus of compounds of formula (IA):



Including the species of:

Determining the scope and contents of the prior art

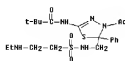
Murakata et al. teaches a genus of compounds of formula (I) as antitumor agents:



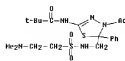
(I)

(57) Abstract: An antitumor agent which contains as an active ingredient a thiazolidine derivative represented by the following general formula (I): [wherein R¹ and R⁴ are the same or different and each represents hydrogen, (un)substituted lower alkyl, (un)substituted lower alkynyl, (un)substituted lower alkenyl, etc.; R³ represents an (un)substituted heterocyclic group, (un)substituted aryl, etc.; R² represents -C(=W)R⁶, etc.; and R⁵ represents hydrogen, -C(=W⁴)R^{6A}, etc.] or a pharmacologically acceptable salt of the derivative.

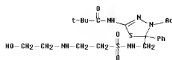
And the following structurally related species within the genus:



(example 163, compound 173 on page 48)



(example 164, compound 174 on page 48)



(example 165, compound 175, on page 48)

Differing slightly by the substitution at the amino position (Et/H, EtOH/H, Me/Me).

Silverman teaches drug discovery, design, and development through modifications of the structure of known molecules showing some activity. For example, Silverman teaches on pages 16-18 homologation of carbon chains. Specifically, the method teaches how lengthening a carbon chain (by increasing successive CH₂ groups) increases pharmacological effects.

Ascertaining the differences between the prior art and the claims at issue

The difference between the Murakata compound and the claims is a single CH₂ group on the amino group within R₄A. The instant claim scope would read on the Murakata compound above, but for the proviso excluding it in the claim.

Resolving the level of ordinary skill in the pertinent art.

One of ordinary skill in the art of pharmaceutical development would be well versed in the teachings of references such as Silverman. One of ordinary skill in the art would consider routine and well within their technical grasp the process of altering the substituents on drug molecules and screen them for activity on a large scale to assess potency.

Considering objective evidence present in the application indicating obviousness

Upon reading the teachings of Murakata, one of ordinary skill in the art would immediately recognize potential to improve the potency of the compounds taught therein through altering the substituents via homologation. Silverman specifically teaches the homologation methodology and provides the underlying physicochemical motivation of altering the lipophilicity of the molecule which would reasonably be applicable to the compound of Murakata. In addition, the Murakata compound is a

homolog of the instant claims, only differing by successive addition of -CH₂- group, thus one of ordinary skill in the art would expect the physical properties of the two compounds to be similar.

In *Eisai Co. Ltd. v. Dr. Reddy's Laboratories Ltd.*, 87 USPQ2d 1452, 1454 (Fed. Cir. 2008), the Federal Circuit clarified the proof of obviousness in structural similarity situations such as this:

Where, as here, the patent at issue claims a chemical compound, the analysis of the third Graham factor (the differences between the claimed invention and the prior art) often turns on the structural similarities and differences between the claimed compound and the prior art compounds. See *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1377 [81 USPQ2d 1324] (Fed. Cir. 2006) (noting that, for a chemical compound, a prima facie case of obviousness requires "structural similarity between claimed and prior art subject matter ... where the prior art gives reason or motivation to make the claimed compositions" (quoting *In re Dillon*, 919 F.2d 688, 692 (Fed. Cir. 1990) (en banc))). Obviousness based on structural similarity thus can be proved by identification of some motivation that would have led one of ordinary skill in the art to select and then modify a known compound (i.e. a lead compound) in a particular way to achieve the claimed compound. See *Takeda Chem. Indus. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356 [83 USPQ2d 1169] (Fed. Cir. 2007). In keeping with the flexible nature of the obviousness inquiry, *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 [82 USPQ2d 1385] (2007), the requisite motivation can come from any number of sources and need not necessarily be explicit in the art. See *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293, 1301 [84 USPQ2d 1198] (Fed. Cir. 2007). Rather "it is sufficient to show that the claimed and prior art compounds possess a 'sufficiently close relationship ... to create an expectation,' in light of the totality of the prior art, that the new compound will have 'similar properties' to the old." *Id.* (quoting *Dillon*, 919 F.2d at 692).

This is further supported by caselaw and the MPEP in section 2144.09(II):

Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH₂- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. In *re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977); see also *In re May*, 574 F.2d 1082, 197 USPQ

601 (CCPA 1978).

Therefore, because the reference teaches homologs of the instantly claimed compounds and the MPEP states that homologs are presumed to possess similar properties, it would have been obvious to one of ordinary skill in the art to modify the alkyl chain length and arrive at the instant invention.

One of ordinary skill in the art would have been guided by the prior art to make the invention as claimed because Murakata teaches the homologous compound, while Silverman teach how to modify the compound to arrive at the instant invention.

Therefore, the claims are obvious.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thornton*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

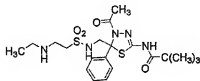
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 13-17 and 22-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 8, 10, 11-13

of copending Application No. 11/909324 in view of Silverman, R. B. (The Org. Chem. of Drug Design and Drug Action, Academic Press, Inc.: San Diego, 1992, pp. 4-51).

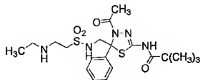
Although the conflicting claims are not identical, they are not patentably distinct from each other because the '324 application claims overlapping subject matter and teaches species that are the same as those referred to in the above 103 rejection, for example:



. Thus, the 103 rejection above is incorporated by reference.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

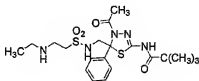
8. Claims 13-17 and 22-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of copending Application No. 11/798214 in view of Silverman, R. B. (The Org. Chem. of Drug Design and Drug Action, Academic Press, Inc.: San Diego, 1992, pp. 4-51). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '214 application claims overlapping subject matter and teaches species that are the same as those referred to in the above 103 rejection, for example:



. Thus, the 103 rejection above is incorporated by reference.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 13-17 and 22-23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 7,425,636 in view of Silverman, R. B. (The Org. Chem. of Drug Design and Drug Action, Academic Press, Inc.: San Diego, 1992, pp. 4-51). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '636 patent claims overlapping subject matter and teaches species that are the same as those



referred to in the above 103 rejection, for example:

the 103 rejection above is incorporated by reference.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims use the phrase "mentioned above" without particularly or distinctly describing what "above" refers to. Thus, one of ordinary skill in the art could not determine the metes and bounds of the claims and the claims are indefinite. The examiner recommends amending the claims to specifically cite what is referred to and not "mentioned."

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 13-19 and 22-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compounds identified as having inhibitory effect with relevant data, does not reasonably provide enablement for the claimed utility of the entirety of the claim scope. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Particularly relevant to the instant case is the issue as to whether the specification provides embodiments allowing use of the claimed invention without requiring undue experimentation by one of ordinary skill in view of the highly unpredictable nature of inhibiting enzymes.

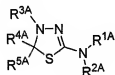
"[An inventor] must not be permitted to achieve . . . dominance by claims which are insufficiently supported and hence not in compliance with the first paragraph of 35 U.S.C. 112. That paragraph requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved." *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).


Accordingly, the critical element here how broad the claims are compared to the level of unpredictability in the art.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation (*United States v. Teletronics*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based upon a single factor but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) and include the following:

Nature of Invention. The nature of the invention involves pharmaceutical compounds for inhibiting enzymes.

Scope of the Invention. The scope of the invention are for a huge genus of compounds



of formula IA (), with in excess of billions of species encompassed by the genus.

State of the Art and Level of Skill in the Art. Although the level of skill in the art is very high, inhibiting enzymes is a very unpredictable art. Kubinyi (3D QSAR in Drug Design: Ligand-Protein Interactions and Molecular Similarity, Vol 2-3, Springer, 1998, 800 pages) teaches that very slight perturbations in the structure of an inhibitor (such as the addition of a methyl group or inversion of a chiral center, see p. 243) can have radical effects on the binding of an inhibitor.

Number of Working Examples and Guidance Provided by Applicant. The applicant provides the following guidance regarding the activity of the compounds claimed:

Compounds 1, 95, 97, 100, 104, 107, 111, 134, 152, 154, 171, 174, 176, 210, 221, ~

238, 264 and the like inhibited the ATPase activity of Eg5 in a

concentration-dependent manner, and IC₅₀ values of the compounds were found to be 2 μmol/L or lower.

Unpredictability of the Art and Amount of Experimentation. The art of using pharmaceuticals to inhibit enzymes is highly unpredictable as described by Kubinyi. In nearly every case, the skilled artisan could not predict *a priori* whether a given pharmaceutical would inhibit an enzyme. When small variations in structure such as the

addition of a methyl group has radical effects on the binding of an inhibitor, without specific guidance or correlations indicating how the structure of species affects its ability to inhibit an enzyme the scope of enablement is constrained to compounds showing substantial similarity to those actually demonstrated to be useful. Furthermore, there would be a huge amount of undue experimentation required in order to synthesize and screen the billions of compounds within the claimed scope.

Considering the above factors, the claims are clearly not enabled for the full scope of the compounds claimed. The examiner recommends either amending the claim scope to only those compounds closely resembling the compounds actually tested and disclosed in the specification or provide additional data and/or structural correlations to guide one of ordinary skill in the art to compounds possessing the asserted utility.

Claim Rejections - 35 USC § 112

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 13-19 and 22-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims contain the amendment except when q=3, which does not have sufficient support in the disclosure. Applicant

cites the following as support:

Support for the amendment to claim 13 can be found throughout the specification. For example, compounds that fall within the scope of claim 13, where $q=3$, include Compounds 237, 238, and 249, described on page 58 and in Examples, 42, 43, and 54, respectively.

The disclosure of the above three compounds conforming to this limitation among the billions of compounds would not convey to one of ordinary skill in the art that applicant was in possession of this new limitation.

Conclusion

The claims are not in condition for allowance.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Havlin whose telephone number is (571) 272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Robert Havlin/
Examiner, Art Unit 1626